

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>  <hr/> <b>THIS DOCUMENT RELATES TO: ETHICON WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS MOTION</b>	<b>MDL No. 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE  
EXPERT TESTIMONY OF STEVEN GOLDWASSER, MD**

Plaintiffs submit this Reply in further support of their Motion to Exclude Expert Testimony of Steven Goldwasser, M.D. (Doc. No 3677).

**INTRODUCTION**

Defendants propose to offer into evidence Dr. Goldwasser's testimony regarding the safety and efficacy of Ethicon's Prolift product. In their Motion, Plaintiffs demonstrated that Dr. Goldwasser is unqualified and did not follow a reliable methodology to testify regarding many of his opinions, including the *adequacy* of Ethicon's warnings and the common knowledge of *other* doctors.

In its Response, Defendants admit or concede the majority of these flaws. Defendant concedes:

- (1) Dr. Goldwasser is not qualified to opine on regulatory requirements or whether Ethicon complied with those requirements. Accordingly, Dr. Goldwasser's labeling opinions are simply based on his personal opinion.
- (2) Dr. Goldwasser admits he does not actually know what other doctors know because different doctors receive different training, read different journals, and have different specialties.

(3) Dr. Goldwasser admits his opinions regarding the absence of evidence showing degradation is wrong.

The Court has consistently excluded doctors from testifying as to many of these subjects.

Consistent with previous rulings and the reasoning behind those rulings, Dr. Goldwasser's opinions should be excluded here.

## ARGUMENT

### **I. DR. GOLDWASSER IS UNQUALIFIED TO RENDER OPINIONS THAT ETHICON ADEQUATELY WARNED AND HAS NOT FOLLOWED A RELIABLE METHODOLOGY.**

Dr. Goldwasser's opinions that Ethicon provided *adequate* warnings in its IFUs should be excluded. First, Dr. Goldwasser is not qualified to offer opinions regarding the regulatory requirements for warnings and admits as much. Second, Dr. Goldwasser did not employ a reliable methodology to reach these opinions, in part, because he cannot articulate any reliable explanation for how he assessed the regulatory requirements and concluded that Ethicon does not need to warn about the relevant complications. Dr. Goldwasser's personal opinions regarding the requirements for warnings are irrelevant, not based on a reliable methodology, and should be excluded. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp 3d 501, 584 (S.D. W. Va. Oct. 17, 2014) (Emphasizing distinction between a doctor testifying as to whether labeling included risks the doctor was aware of and testifying whether labeling was *adequate*).

Dr. Goldwasser is not qualified to testify on these topics. Ethicon explicitly concedes that "Dr. Goldwasser does not offer opinions that Prolift's labeling is 'adequate' from a regulatory perspective." Defendants' Memorandum in Opposition at 4 (Doc. No 3754) ("Response"). As the Court has consistently held, an "expert must possess additional expertise to offer testimony about what information should or should not be included in an IFU." *See e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 10 (S.D. W. Va. Aug. 31, 2016) (Doc.

No. 2701) (Memorandum Opinion and Order – Daubert Motion re: Brian J. Flynn, M.D.) (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202 at \*14 (S.D. W. Va. Feb. 7, 2015)); *see also See Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, \*44 (S.D. W. Va. May 9, 2016) (holding that “without additional expertise in the specific area of product warnings, a doctor, such as a urogynecologist, is not qualified to opine that a product warning was adequate merely because it included the risks he has observed in his own practice.”). Dr. Goldwasser does not possess such expertise.

Further, Dr. Goldwasser’s opinion that Ethicon’s warnings is based on his assumption that Ethicon is excused from warning about the applicable complications. However, Dr. Goldwasser has not explained how he disregarded the extensive regulatory labeling requirements and determined that one specific subsection of the CFR regarding labeling completely excuses Ethicon from its labeling obligations. Likewise, Ethicon does not explain how Dr. Goldwasser reached this grandiose conclusion.

Dr. Goldwasser is not qualified, did not follow a reliable methodology, and did not reliably assess all the relevant regulations – his opinions regarding the adequacy of Ethicon’s warnings are simply based on his own personal belief and not any reliable objective standard. Accordingly, these and other legal opinions should be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (holding that “opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013) (excluding testimony regarding legal conclusions such as manufacturer “failed to adequately disclose adverse risks associated with their products” and manufacturer “failed to warn on its label”).

**II. DR. GOLDWASSER'S ADMITS HIS OPINION IS WRONG REGARDING THE ABSENCE OF EVIDENCE SHOWING DEGRADATION AND ALL OF HIS DEGRADATION OPINIONS ARE BASED ON AN UNRELIABLE METHODOLOGY.**

In his Report, Dr. Goldwasser opines that he is not aware of any evidence showing that polypropylene degrades. He necessarily admitted this broad statement was completely wrong. He testified, “There is evidence on **both** sides of the debate, correct.” Transcript of Dr. Stephen Goldwasser Deposition, 3/29/2017, 222:8-17 (attached as exhibit C to Motion, Doc. No. 3677) (“Goldwasser dep.”). Dr. Goldwasser cannot be permitted to testify as to an opinion that he admits is completely wrong.

Dr. Goldwasser’s other opinions regarding degradation are also the product of an unreliable methodology. Dr. Goldwasser’s other degradation opinions essentially involve his opinion that degradation does not happen but if it does, it is not clinically significant. While these two statements cannot coexist under a reliable methodology, they are both undermined by his lack of qualifications and refusal to address the contrary evidence he was aware of.

Dr. Goldwasser is not uniquely qualified in biomaterials, histopathology, or degradation of polymers. Dr. Goldwasser admits he has never looked at mesh under a microscope or electronic scanning microscope. Goldwasser dep. 196:2-18. It is unsurprising that Dr. Goldwsaser has never seen the microscopic cracking indicative of degradation, if he has never looked at the mesh under a microscope. Dr. Goldwasser simply has no personal experience looking for or evaluating degradation.

Additionally, Dr. Goldwasser’s opinions regarding degradation are not based on any direct evidence or personal experience, but rather based on his opinion that no evidence exists. As the Court has previously acknowledged, absence of evidence is not evidence of absence. *Tyree v.*

*Boston Sci. Corp.*, 54 F. Supp 3d at 583-84 (citing the infamous Carl Sagan aphorism). Dr. Goldwasser unreliable assumes that because *he* is not aware of any evidence, none exists (despite acknowledging evidence actually exists on both sides of the debate). Even in its Response, Ethicon does not point to any evidence to support Dr. Goldwasser's broad opinions regarding degradation.

Dr. Goldwasser admits some of his degradation opinions are just wrong. Dr. Goldwasser is not uniquely qualified and has no direct personal experience regarding degradation. Finally, Dr. Goldwasser's primary basis for his degradation opinions is that he is not aware of any evidence – but this logical fallacy is unreliable. Dr. Goldwasser's opinions regarding degradation should be excluded because they are not supported by sufficient data and not the product of a reliable methodology.

**III. DR. GOLDWASSER'S PERSONAL OPINION REGARDING WHAT IS "COMMONLY KNOWN" IS NOT THE PRODUCT OF A RELIABLE METHODOLOGY, AND IS NOT BASED ON SUFFICIENT FACTS.**

Dr. Goldwasser seeks to testify that he knows what all surgeons know. *See Report at 31.* Unless Dr. Goldwasser is clairvoyant (something not disclosed on his CV), it is impermissible for Dr. Goldwasser to offer such speculation under the guise of expert testimony. Dr. Goldwasser has not established that these opinions are based on sufficient facts or the result of a reliable methodology. Instead, he necessarily admits extensive differences exist between different doctors. Consistent with earlier rulings and because Dr. Goldwasser has not followed a reliable methodology here, these opinions should be excluded. *See Trevino*, 2016 WL 2939521, at \*39 (excluding opinion that "surgeons are well aware of clinical implications of complications" when expert has not established opinions are the result of a reliable methodology); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 7 (S.D. W. Va. Sept. 2, 2016) (Doc. No. 2727) (Memorandum Opinion and Order – Daubert Motion re: Michael Karram, M.D.) (The

Court has “consistently prohibited state-of-mind testimony, as allowing such testimony would usurp the jury’s fact finding duties.”).

Dr. Goldwasser essentially admits this opinion is unreliable and not based on sufficient facts. Dr. Goldwasser admits different doctors have different knowledge based on differences in training, personal experience, specialties, reading different journals, and attending different medical seminars. Goldwasser dep. 62:19-63:24. Similarly, Dr. Goldwasser admits he has no evidence showing what all doctors are aware of. Goldwasser dep. 222:18-223:1. Ethicon completely ignores all of Dr. Goldwasser’s admissions.

Instead of addressing any of Dr. Goldwasser’s admissions illustrating the unreliability of his opinions, Ethicon spends four pages arguing about qualifications and relevance. Ethicon’s lengthy arguments miss the point – the focus here is whether Dr. Goldwasser’s opinions are based on sufficient data and whether his opinions are based on a reliable methodology. Dr. Goldwasser has admitted he cannot reliably know what other doctors know and has admitted numerous differences exist between different doctors. Ethicon concedes these fatal flaws.

Dr. Goldwasser has not established that he followed a reliable methodology or that this opinion is based on sufficient facts. Instead, he has admitted numerous differences exist that highlight the unreliability of these opinions. Consistent with the Court’s previous rulings, Dr. Goldwasser’s opinions regarding what is commonly known and what physicians are acutely aware of should be excluded.

## CONCLUSION

For the reasons discussed above and in Plaintiffs' Motion, Dr. Goldwasser should not be permitted to testify as to opinions where he is not qualified, where the opinions are not supported by sufficient facts or data, and where the opinions are not the product of a reliable methodology.

Respectfully submitted this 4<sup>th</sup> day of May, 2017.

*/s/ Joseph J. Zonies*  
Joseph J. Zonies, Esq.  
Zonies Law LLC  
1900 Wazee Street, Suite 203  
Denver, Colorado 80202  
(720) 464-5300  
(720) 961-9252 fax  
[jzonies@zonieslaw.com](mailto:jzonies@zonieslaw.com)

*/s/ Thomas P. Cartmell*  
Thomas P. Cartmell, Esq.  
Jeffrey M. Kuntz, Esq.  
Wagstaff & Cartmell LLP  
4740 Grand Avenue, Suite 300  
Kansas City, MO 64112  
816-701-1102  
Fax 816-531-2372  
[tcartmell@wcllp.com](mailto:tcartmell@wcllp.com)  
[jkuntz@wcllp.com](mailto:jkuntz@wcllp.com)

*/s/ D. Renee Baggett*  
Bryan F. Aylstock, Esq.  
Renee Baggett, Esq.  
Aylstock, Witkin, Kreis and Overholtz, PLC  
17 East Main Street, Suite 200  
Pensacola, Florida 32563  
(850) 202-1010  
(850) 916-7449 (fax)  
[rbaggett@awkolaw.com](mailto:rbaggett@awkolaw.com)  
[baylstock@awkolaw.com](mailto:baylstock@awkolaw.com)

**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing **PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE EXPERT TESTIMONY OF STEVEN GOLDWASSER, M.D.** on May 4, 2017, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Joseph J. Zonies

Joseph J. Zonies